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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/950,003	09/12/2001	Pasqua Oreste	MARGI 27 P1	9777

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EXAMINER	
KRISHNAN, GANAPATHY	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/950,003	ORESTE ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34,38-53 and 56-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *14-34* is/are allowed.

6)☒ Claim(s) *1-13,38-53 and 56-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 7/29/2004 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 35-37, 54-55 have been canceled.

2. New Claims 71-77 have been added.

3. Claims 4, 11-13, 17 have been amended.

4. Remarks drawn to rejections under double patenting, 35 USC 112, first paragraph, 112, second paragraph.

Claims 1-34, 38-53 and 56-77 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Any allowability of claims indicated in the previous office action has been withdrawn and the following rejections are made of record.

Double Patenting

The statutory double patenting (35 USC 101) of claims 1-10 as claiming the same inventions as that of claims 1-10 of copending application No. 10/240606 ('606 application) is being maintained. Applicants argue that inventors herein have not authorized the filing of application No. 10/240606 and the office should cancel claims 1-10 from the '606 application and the instant application should be allowed. This is not found to be persuasive. The office does not have the authority to cancel claims without the permission of the inventors of the '606 application.

The following new rejection is made of record.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 38-53 and 56-62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 30 and 31of copending Application No. 10/469,037 ('437 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claims 38-53 and 56-62 are drawn to a sulfated polysaccharide with similar structure, sulfation percentage ranges and degree of sulfation that overlap with those recited in claims 30-31of copending '467 application.

It would have been obvious to one of ordinary skill in the art that the instant claims are substantially overlapping with the claims of the copending application as stated above. The instant claims should recite limitations that are patentably distinct from those of the claims of the copending application.

Claims 4, 11-13 and 71-77 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending

Application No. 10/240606 ('606 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claims 4, 11-13 and 71-77 are drawn to a process of preparation of K5 polysaccharide that recite process limitations comprising N-deacetylation, N-sulfation, C5 epimerization, oversulfation, O-desulfation, 6-O-sulfation and N-sulfation in the presence of glucuronosyl C5 epimerase and divalent cations. These same process limitations are also seen in claims 1-10 of the copending '606 application.

It would have been obvious to one of ordinary skill in the art that the instant claims are substantially overlapping with the claims of the copending application as stated above. Instant claims 4, 11-13 and 71-77 should recite limitations that are patentably distinct from those of claims 1-10 of the copending '606 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The rejection of claims 66 and 70 under 35 USC 112, first paragraph is being maintained for reasons of record. Applicants argue that the instant claims find support in the specification and have cited prior art in support of their arguments. This is not found to be persuasive. The specification is not enabling for the prevention of thrombosis. The cited prior art also do not provide any examples that show prevention of thrombosis. Just a mere statement in the prior art that their compounds are useful for prevention without sufficient data to back up their claim is not sufficient for an enabling disclosure for prevention of thrombosis.

The rejection of claims 4-34 under 35 USC 112, second paragraph has been overcome by amendments.

The rejection of claims 64 and 68 under 35 USC 112, second paragraph for recitation of the term "controlling" is being maintained for reasons of record.

Applicants argue that a skilled artisan would understand that the verb 'to control" is used to mean "to reduce the incidence or severity to an innocuous level" as defined in Webster's Third New International Dictionary. This is not found to be persuasive. The term control is interpreted to mean an increase or decrease as needed inorder to bring an incidence to an innocuous level, not just reduce the incidence. Hence a clear definition of the said term is needed in the claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 63, 65, 67, 69 and 71-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 63 and 65 depend from cancelled claim 35. This renders the claims indefinite. Claims 67 and 69 are also rendered indefinite since they depend from claims 65 and 67 respectively.

In claim 71 it is not clear what "containing from 25 to 50% on weight of the chains" means.

Claims 72-77 that depend from the rejected base claim 71 are also rendered unclear and are rejected for the same reasons.

Conclusion

1. Claims 1-13, 38-53 and 56-77 are rejected.

2. Claims 14-34 drawn to preparation of glycosaminoglycans involving the specific non-obvious step of partial O-desulfation using DMSO/methanol is neither taught or fairly suggested by the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK

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